Study Ontology User Guide

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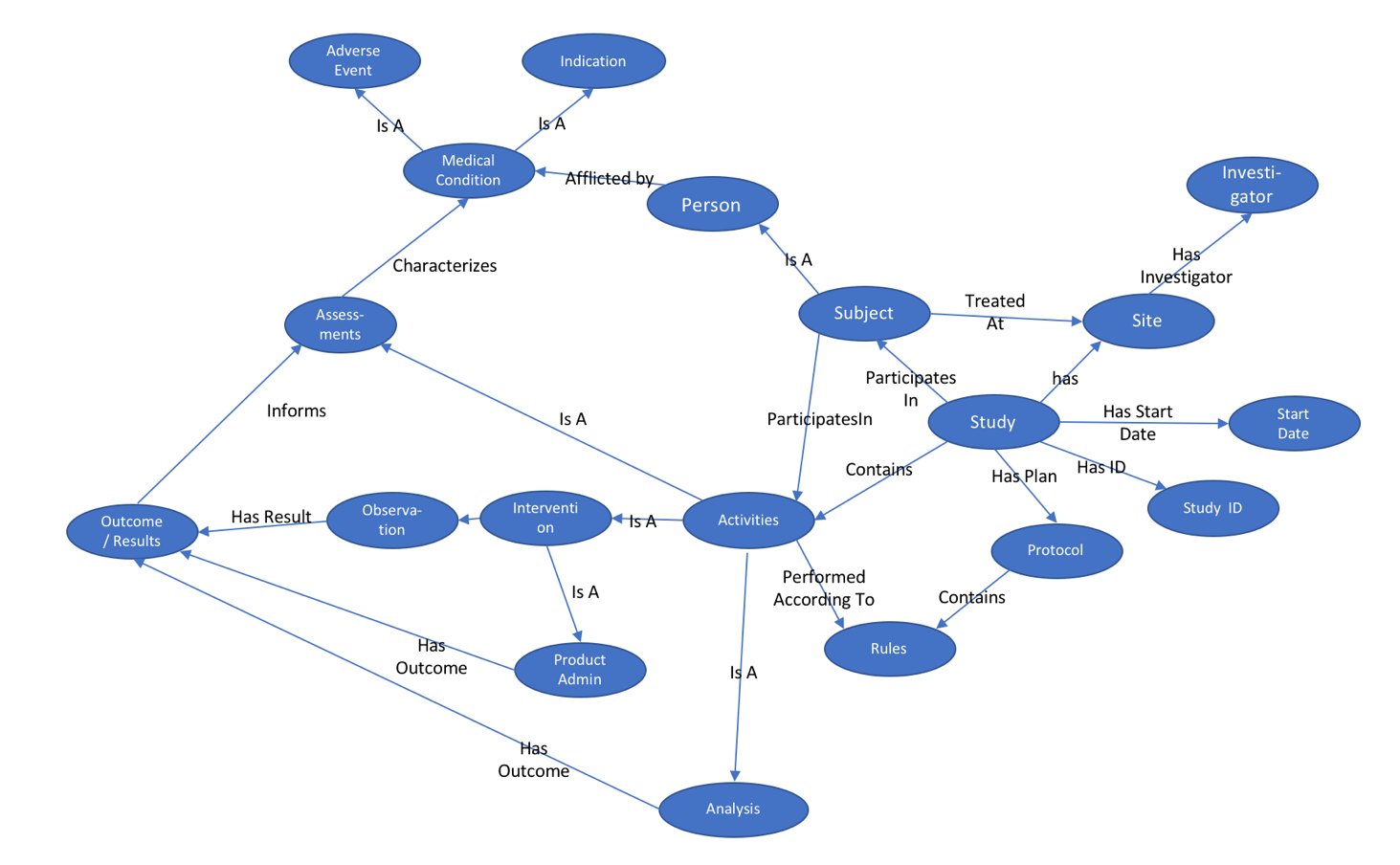


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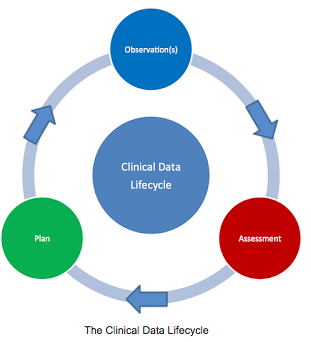
# Introduction

This document provides detailed information on the Study Ontology being developed for the Clinical Trial Data to RDF Project within PhUSE. Because of the narrow scope of that project, the Ontology is appropriately also narrow in scope, but can be expanded in an iterative fashion to support future use cases. The classes and properties align with BRIDG and HL7 RIM wherever it makes sense to do so, but also intentionally deviates from these models when necessary. The Study Ontology is available at [GitHub](https://github.com/phuse-org/CTDasRDF) as an RDF/OWL file study.ttl. This is a living document and subject to change at any time. For questions or comments, please contact [aoliva@semanticallc.com](mailto:aoliva@semanticallc.com).

# Study Ontology “Core Classes”

A study is a collection of Activities (e.g. Interventions, Observations, Analyses) performed on Human Study Subjects and their data according to certain protocol-specified Rules. Human Study Subjects often have medical Events (e.g. Medical Conditions, Adverse Events), which are the target of medical Interventions. The Interventions often involve a Medical Product Administration, such as a Drug, These classes form the study ontology “core.” Additional related classes are explained later in this document.

These core classes are related to each other based upon the ages-old physician practice of documenting biomedical information on individual patients using the SOAP approach: “Subjective Observations,” “Objective Observations,” “Assessment,” followed by “Plan.” The study ontology class “Observation,” “Assessment,” and “Intervention” intentionally map to these SOAP categories to document a subject’s clinical data lifecycle over time.



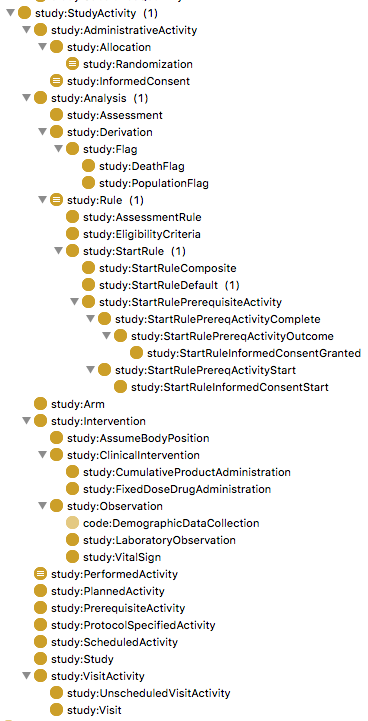
As much as possible, Aristotelian definitions are used to define a class, e.g. a [subclass] is a [class] with certain [distinguishing features]. For example, a FordCar is a Car that is manufactured by the Ford Motor Company. Similarly, a HumanStudySubject is a Person who participates in any StudyActivity.

# Study Ontology Classes

Most classes in the Study Ontology fall under the StudyComponent Class. The exceptions generally fall into timing concepts. These are generally found under the standard Time Ontology classes such as Instant and Interval.

The StudyComponent Class has two main classes: StudyActivity and Entity. Each is presented in its own section along with the important subclasses.

# Study Activity Taxonomy



# Class: StudyActivity

SubClassOf: StudyComponent

Definition: Any activity associated with the planning, conduct, analysis, and interpretation of a Study.

Discussion: This is quite broad so StudyActivity has numerous subclasses. The key properties of a StudyActivity are the following: (i.e. ?property rdfs:domain study:StudyActivity triple exists)

* activityStatus, e.g. completed, not done, started, incomplete
* derivedFlag, the studyActivity derives new data from existing data (e.g. Y, N)
* groupID, non-specific grouping ID
* activityInterval, time interval during which the activity takes place
* category, non-specific category information for the activity
* performer, the entity that performed the activity
* startRule, the rule that describes when the activity should take place
* subActivity, a dependent activity related to the studyActivity (e.g. diastolic BP with a BP measurement activity
* subcategory, non-specific sub-category information for the activity
* laterality, anatomic laterality describing where the activity takes place, e.g. LEFT, RIGHT
* outcome, the result of the activity having taken place
* reasonNotDone, the reason the activity was not performed when the activityStatus “Not Done” is reported
* sponsorDefinedID, non-specific sponsor provided identifier for the activity.

StudyActivities also are the target of certain important relationships…the most important of which is arguably a HumanStudySubject participatesIn a StudyActivity.

The StudyActivity class has numerous important subclasses shown below.

## Class: Intervention

Subclass of: StudyActivity

Definition: A study activity that involves an interruption to the study subject's normal daily routine for the purpose of observing the subject's physical, psychological, or physiological state, and/or mitigating the effects of a medical condition.

Note: The definition of an Intervention includes Observations and is broader than the BRIDG definition (which otherwise does not include Observations). It recognizes that an Observation requires a process of intervention to record the observation. Information about that process is often important since the act of observing may have an impact on the result (e.g. recording a BP measurement in an obese individual using a blood pressure cuff that is too small).

Key SubClasses: studyAssumeBodyPosition, study:ClinicalIntervention, study:Observation

### Class: AssumeBodyPosition

SubClassOf: Intervention

Definition: An Intervention whose intent is to observe the Person's body position and change it to the desired body position, usually in preparation for another intervention.

### Class: ClinicalIntervention

SubClassOf: study:Intervention

Definition: An Intervention whose intent is to have a clinical effect on (e.g. treat, prevent) a Medical Condition

Important subclasses include study:CumulativeProductAdministration (The act of administering/taking a Product over time; there may be breaks or the dose may change over time) and also study:FixedDoseDrugAdministration (A ClinicalIntervention where a fixed dosed of a drug product is administered over a documented interval of time.

### Class: Observation

SubClassOf: Intervention

Definition: An Intervention whose intent is to measure of the physical, physiological, or psychological state of a Person.

Note: A (Clinical) Observation is ideally observed by a qualified individual, following a standard process, but without implying a cause. Many clinical observations simply reflect a normal physiological state. e.g. BP 120/80 mmHg. The classification of an Observation as a subclass of Intervention deviates from BRIDG and other models in that it recognizes that an observation requires intervening in the Person's normal routine and that intervention method may impact the observation result.

Important subclasses include study:VitalSign, code:DemographicDataCollection, and study:LaboratoryObservation.

## Class: Analysis

SubClassOf: StudyActivity

Definition: An examination, sometimes via a mathematical manipulation, of one or more observations to obtain a result.

Note: The important point here is that data already exist as input to an analysis. No additional data collection on the HumanStudySubject is needed.

Key SubClasses: study:Assessment, study:Derivation, study:Rule

### Class: Assessment

SubClassOf: Analysis

Definition: An examination of one or more clinical observations to identify and/or characterize a Medical Condition.

Assessments are conducted by medical staff constantly and often are not well documented in a clinical trial. When formalized, the process is also known as an adjudication and often performed by an adjudication committee. Causality assessments are a type of Assessment activity.

### Class: Derivation

SubClassOf: Analysis

Definition: An Analysis that examines one or more observations for a HumanStudySubject and obtains a result that is also specific for that HumanStudySubject.

Note: The key is that the result (e.g. derived variable) belongs to the HumanStudySubject. In contrast the result of an efficacy or safety analysis is specific for the study population, not the individual subject.

Key subclass: study:Flag (e.g. a derivation where the result/outcome is binary e.g. Y/N)

### Class: Rule

SubClassOf Analysis

Definition: An Analysis that examines whether one or more observations or derivations meet certain pre-defined target(s). If the target is met, then the rule outcome is set to true, otherwise it is set to false if the target is not met.

Note: Examples include Age >=18 and Sex = Female.

## Class: AdministrativeActivity

SubClassOf: StudyActivity

Definition: A StudyActivity that is performed primarily to facilitate administrative execution of a study. These are activities that are not routinely performed during ordinary patient care outside of a study setting.

Key subclasses: study:InformedConsent, study:Allocation (study:Randomization)

## Class: Arm

SubClassOf: StudyActivity

Definition: A path though the study which describes what activities the study subject or experimental unit will be involved in as they pass through the study (BRIDG 5.0)

## Class: PerformedActivity

SubClassOf: StudyActivity

Definition: An Activity that was performed on a specific time interval or instant. It has activity status as COMPLETE.

## Class: PlannedActivity

SubClassOf: StudyActivity

Definition: An Activity that is or was intended to occur. It is associated with a performer and/or a participant and is associated with a start rule that is described in the protocol.

## Class: PrerequisiteActivity

SubClassOf: StudyActivity

Definition: A StudyActivity whose Date functions as a time point reference for other activities.

Note: For example: An activity to assume a supine body position can be a prerequisite activity for a BP measurement 5 minutes later. An activity outcome could be a medical condition, e.g. the ActivityOutcome can be a migraine headache, which triggers another activity: drug administration.

## Class: ProtocolSpecifiedActivity

SubClassOf: StudyActivity

Definition: A StudyActivity that is specified in the Protocol to occur in the Study. It is associated with a start rule but not necessarily with a subject. A protocol specified activity is instantiated for each Subject in the study. The instance of a protocol specified activity becomes a Planned Activity.

## Class: ScheduledActivity

SubClassOf: StudyActivity

Definition: An activity that is or was scheduled to occur on a HumanStudySubject at a specific date/time

## Class: Study

SubClassOf: StudyActivity

Definition: A research project conducted on HumanStudySubjects whose objectives are to test or confirm hypotheses concerning the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic.

Note: The BRIDG concept Study is broader in that it includes nonclinical and in vitro studies whereas this ontology is limited to human studies.

## Class: VisitActivity

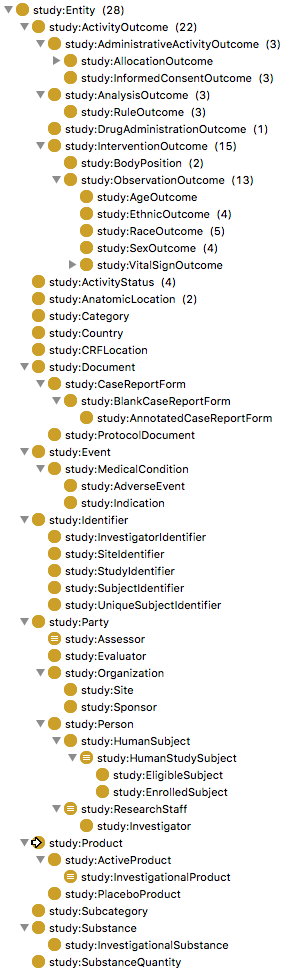
SubClassOf: StudyActivity

Definition: A study activity that takes place or begins during a visit.

Note: A drug administration activity may begin during the visit and may continue past the visit end date.

Key subclasses: Visit (Any StudyActivity whose main focus is an interaction with the investigational staff, usually intended to collect and/or assess observations) and UnscheduledVisitActivity (Any StudyActivity that takes place during an UnscheduledVisit).

# Entity Taxonomy



# Class: Entity

SubClassOf: StudyComponent

Definition: [deferred]

The Entity class has numerous subclasses that are described below.

## Class: ActivityOutcome

SubClassOf: Entity

Definition: An Entity that is the outcome of a Study Activity. For an Observation, this is the result of the observation.

## Class: ActivityStatus

SubClassOf: Entity

Definition: The Status or state of a StudyActivity. For example, Completed, Started, Not Done, Incomplete.

## Class: AnatomicLocation

SubClassOf: Entity

Definition: The location on the body where an activity/process occurs or an entity is located.

## Class: Category

SubClassOf: Entity

Definition:

## Class: Country

SubClassOf: Entity

Definition: [deferred]

## Class: CRFLocation

SubClassOf: Entity

Definition: [deferred]

## Class: Document

SubClassOf: Entity

Definition: A written record

Key subclasses: ProtocolDocument, CaseReportForm

## Class: Event

SubClassOf: Entity

Definition: An occurrence; Something that happens. Events persist in time.

Events has important subclasses: MedicalCondition, AdverseEvent, Indication

### Class: MedicalCondition

SubClassOf: Event

Definition: An event that is a disease, injury, disorder, or transient physiologic state that interferes or may interfere with well-being. A medical condition persists in time.

Note: Medical conditions are the target of medical interventions. Medical conditions explain the presence of clinical observations. Most clinicians will agree that pregnancy is a medical condition because it benefits from medical intervention (e.g. prenatal care) to minimize complications to the mother and unborn child

### Class: AdverseEvent

SubClassOf: MedicalCondition

Definition: An adverse Medical Condition that emerges or worsens following a Medical Intervention, including the use of a drug. Note: there is no presumption of causality.

### Class: Indication

SubClassOf: MedicalCondition

Definition: A Medical Condition that is the target of an Intervention.

## Class: Identifier

SubClassOf: Entity

Definition: [deferred]

## Class: Party

SubClassOf: Entity

Definition: A Person or an Organization.

### Class: Organization

Definition: [deferred]

Key subclasses: Site, Sponsor

### Class: Assessor

Definition: A Party that performs an Assessment (See study:Assessment)

### Class: Evaluator

Definition: [deferred; this term is used in CDISC but is not defined; need to distinguish between Evaluator and Assessor]

### Class: Person

Definition: [deferred]

Key subclasses: ResearchStaff, Investigator, HumanSubject, HumanStudySubject, EnrolledSubject

## Class: Subcategory

SubClassOf: Entity

Definition: [deferred]

## Class: Product

SubClassOf: Entity

Definition: [deferred]

Key Subclasses: ActiveProduct, InvestigationalProduct, PlaceboProduct

## Class: Substance

SubClassOf: Entity

Definition: [deferred]

Key Subclass: InvestigationalSubstance

## Class: SubstanceQuantity

SubClassOf: Entity

Definition: A substance of a fixed mass, e.g. propranolol 20 mg

# Temporal Concepts Taxonomy

